K071782

micromed ELETTROMEDICALI

510(k) Summary

1.1.1 Submitter

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1.1.2 Official Contact Person

Monica Camillo

1.1.3 Summary preparation date

October 9th , 2007

JAN 10 2008

1.1.4 Device identification

BRAIN SPY PLUS holter polygraph
MORPHEUS polysomnograph
EMBLA TITANIUM polysomnograph

- recommended classification regulation: **21 CFR 882.1400**
- class **II**
- panel: **Neurology**
- product code: **GWQ**

1.1.5 Devices to which substantial equivalence is claimed:

- K042150 Xltek Trex
- K050425 Grass Telefactor Aura PSG
- K031202 Braebon MEDIPalm

1.1.6 Device description

The device function is the acquisition of bioelectric signals, as is typical for EEG amplifiers and holter recorders. The device receives and amplifies patient input signals, converts them to digital format, packs them by a programmable logic and sends them to an internal microcontroller. The microcontroller stores them in a RAM buffer, from where they are written at defined time to the Compact Flash memory. The data can be viewed directly on the display or downloaded by using either specific interface modules (BQUSB towards the USB port of the PC or BQNET towards an Ethernet link) or the built-in Bluetooth® link. Data can also be read directly from the Compact Flash card via a memory card reader. In PC a typical polysomnographic analysis software application manages the storage and the on-line or off-line display of the data. In the main version, the device is provided with 32 input channels:

- 24 channels for EEG (BW: 0.15-220 Hz)
- DC channels (0-330 Hz)
- 2 channels for the built-in flow sensors
- 2 channels for external inductive belts (respiratory effort sensors)
- 1 channel for a built-in body position sensor
- 1 channel for digital data from the oximeter (SpO_2, heart rate and plethysmographic signal)

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The device is enclosed in a (2.5 -> 3.5) h x 7.5 x 11.4 cm plastic case and weighs 200g. It is powered by 2 AA 1,5V alkaline batteries, by the BQUSB interface (via the connected PC) or the BQNET module (via separate AC mains adapter). .

The device has a LCD allowing the menu to be displayed; the display gives information on the recording mode, acquisition time, remaining memory, impedance measure and allows the rough display of the acquired traces both on-line and after the recording. The user interface includes 4 membrane keys enclosed in the label below the display.

The device has no patient contacting parts. Input signals are collected by commercially available accessories like EEG electrodes, oximeter sensors, cannulae and respiratory effort sensors (elastic band). The patient and operator can eventually touch the plastic external enclosure but the device is usually worn above the clothes in a synthetic fabric bag.

The manufacturer does not intend to limit the utility of this device by listing a finite set of commercially available sensors. The device is only a recorder that receives and records input form sensors and subsequently downloads those recordings to a PC resident polysomnological application software for clinical analysis: it is very versatile in the range of input sensors that can be used in various sleep study clinical settings. The sensors, kits and application software are not intended to be included in this application for clearance.

For connection with the sensors and the PC, the devices are provided with:

- touch proof connectors for patient electrodes (EEG channels)
- touch proof (BRAIN SPY PLUS) or 3-pin connector (MORPHEUS/TITANIUM) connectors for DC channels
- 1 screw-lock and 2 hose barb connectors for flow sensor cannulae (MORPHEUS/TITANIUM version)
- 2 connector for the respiratory effort elastic band (MORPHEUS/TITANIUM version)
- 3-pin (MORPHEUS/TITANIUM) or 4-pin (BRAIN SPY PLUS) connectors for the oximeter
- 4 pin push-pull connector for the connection to the BQUSB or BQNET module.

The communication lines with the BQUSB or BQNET module are optically isolated.

In the PC data coming from either USB, Ethernet or Bluetooth® ports are then acquired by an acquisition software. The submitted device is supported by PC based application software such as Embla's Somnologica Studio (version 5.1), or Micromed's System Plus (version 1.03). The application software is not intended to be included in this application for clearance.

Battery power is provided to make the device safer, ergonomic and able to acquire good signals even in electromagnetically noisy environment. Low power consumption allows 24 hours of consecutive recording with a pair of standard alkaline battery. Maximum power consumption is 80-100 mA, plus 30 mA in wireless transmission mode. In stand-by, the power consumption is less than 100µA.

When voltage and communication signals are present on the cable connection, the device is powered by the USB interface modules through a DC/DC converter.

The device can also be connected to the PC through a radio (Bluetooth®) link using the RADIOEEG built-in module. The microcontroller communicates with the radio module through its serial port and transmits the data to a Bluetooth® receiver on the PC. .

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The Compact Flash storage memory capacity determines the duration of the recording according to the number of the channels used. The commercially available (1 GB) allow more than 24 hours recording of 32 channels at 128 Hz sampling rate, without data compression. If data compression algorithm is used, recording time can be increased by 25-30%.

The device family is composed of two basic models all sharing the same case, internal hardware and firmware. The BRAIN SPY PLUS model is obtained by a MORPHEUS model without the internal sensors and with a different input panel (less and different connectors). The Embla TITANIUM model is identical to MORPHEUS, differing only in labeling (distributor brand and device name).

1.1.7 Devices intended use

The devices are intended to acquire, store, and transfer biophysical signals to separate polysomnographic analysis software available with marketed systems for EEG and Sleep Studies. .

The devices are intended for use by physicians, technicians, or other medical professionals that are trained in EEG and/or PSG in any location within a medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional. The device will be available on all patient populations, as determined by a trained professional.

These devices do not provide alarms and they are not intended for use as an automated apnea monitor.

The devices do not make any judgment of normality or abnormality of the displayed signals.

1.1.8 Technological characteristics and product performance

The device shares with the predicates many technological characteristics.

The EEG and polysomnography devices on the market have different number of channels and integrated sensors, depending on the intended use (mainly PSG, mainly EEG or both uses).

When the body position, respiratory effort and flow measurement sensors are not integrated in the devices, external devices with the same functions are used in connection with the recorders. Brain spy Plus, like some of the predicate, can achieve equivalent performance with respect to the major models by acquiring signals from the external sensors.

Also oximeter circuit can be internal or external, but they are based on two major manufacturers technology (Nonin Inc. and Masimo): oximeters based on technology provided from Nonin are used in Braebon and Grass Telefactor products.

The devices are hence comparable for channel numbers, characteristics and features availability (integrated sensors and/or dedicated channels).

All the devices have small size, limited weight and a plastic enclosure. Some of these are provided with a fixed base station, other includes all the functions in the portable part.

Power supply is provided by internal batteries. Some devices use standard disposable batteries which do not require the use of a battery charger, others use rechargeable batteries.

Expected battery life is comparable or greater than those declared for the other devices.

Some of the predicates (e.g. Braebon MEDIPalm and Grass Telefactor Aura-PSG devices) can be used in tethered (on-line) mode, connected to the PC or/and a base station. When used in this mode the devices can be powered directly by the remote power source (USB cable and proper isolation or medical grade power supply). An equivalent degree of safety is achieved in the device through compliance with IEC 60601-1 standard.

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All the devices are based on the same working principle: biopotentials and data from patient-connected sensors are acquired, amplified, digitized, and stored in the internal compact flash memory.

For all the devices data stored in the flash card can be transmitted (through cable and in some devices via a radio link using the ISM 2.4 GHz band and low RF output power) to a remote PC for signal check contemporarily to the acquisition. Data can also be downloaded at the end of the exam through the interface connection to the PC or removing the card.

Card capacity is always sufficient to store whole-night examination data.

All the devices can be remotely controlled by the separate polysomnographic analysis software installed on the PC, which sold separately and not included in this application for clearance, which also performs the signal analysis. None of the devices directly analyzes the collected data. Verification and validation test on the firmware shows that the device is correctly and safely controlled through the remote commands.

Integral keys and display to show menu and check the signals directly from the device are also available in one of the predicate devices. Verification and validation test on the firmware shows that the device is correctly and safely controlled through the local commands

All the devices contact the patient only through the accessories connected to the inputs (electrodes, oximeter sensor, cannulae, and elastic belts for respiratory efforts) which are separate devices. Hence, no questions on patient-contacting material arise for these devices: the device can be carried in a bag intended to be worn over a garment.

1.1.9 Performance specifications, including any testing.

Safety Tests have been performed to verify compliance with IEC 60601-1/UL2601-1, IEC 60601-1-1 and IEC 60601-2-26 to ensure that there are no potential hazards on patients, other persons, or the surroundings.

Electromagnetic Compatibility tests according to IEC 60601-1-2 have been performed to ensure no intolerable magnetic disturbances are introduced into its electromagnetic environment.

Immunity tests to IEC 60601-1-2 have been performed to ensure that the EEG equipment has the ability to operate satisfactorily in its electromagnetic environment

No specific guidance document on performance is required for EEG/PSG devices.

The device capability is equivalent to the features specified for predicate devices.

Verification of firmware ensures that the system conforms to all the system design requirements.

Functional testing was performed to confirm that the devices are capable of meeting their stated performance specifications.

1.1.10 Conclusions

Based on the above discussion, the risk analysis and testing done and the table of comparison between the devices, Micromed Morpheus, Micromed Brain Spy Plus and Embla Titanium devices are substantially equivalent to the predicate devices as identified in the Identification of Predicate Devices section.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
9200 Corporate Boulevard
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JAN 10 2008

Micromed S.P.A.
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Mr. Jan Van Lochem
4377 County Line Road
Chalfont, PA 18914

Re: K071782
Trade/Device Name: Micromed Brain Spy Plus, Morpheus, Embla Titanium Devices
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: December 21, 2007
Received: December 26, 2007

Dear Mr. Van Lochem:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K071782**

Device Name: **EMBLA TITANIUM; MICROMED MORPHEUS; MICROMED BRAIN SPY PLUS**

Indications for Use:

The devices are intended to acquire and store physiological signals for EEG and Sleep Studies, and to transfer the data to separate polysomnographic analysis software.

The devices are intended for use by physicians, technicians, or other medical professionals that are trained in EEG and/or PSG .

Prescription Use ___YES____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __NO_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071782